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John T. Kilcoyne

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EXAMINER

NGUYEN, HUONG Q

ART UNIT

PAPER NUMBER

3736

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/687,336	Applicant(s) KILCOYNE ET AL.	
	Examiner HELEN NGUYEN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 2/18/2009. Claim 50 is amended overcoming the previous claim objection. **Claims 50-58** remain pending and under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 50-58** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Specifically, it does not appear that that Applicant's disclosure provides support for the amendment to Claim 50 reciting "the plurality of sensors is capable of independently measuring a physiological parameter indicative of gastroesophageal reflux different from other physiological parameters indicative of gastroesophageal reflux measured independently by other sensors." Although the specification discloses that the plurality of sensors may each measure a different physiological parameter indicative of gastroesophageal reflux, see p.27 line 1-5, there does not appear to be a requirement for the sensors to independently measure said physiological parameters. In fact, Applicant's disclosure appears to teach the opposite, mainly that one physiological parameter may

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measure another parameter in which it is dependent upon, such as measuring both pH and temperature and using the temperature reading to adjust the pH value, see p.10 line 15-20.

5. Also, due to the amendment it is unclear what is meant by “other sensors” and thus in the rejection that follows, it is assumed said other sensors are external sensors.

6. Applicant is requested to point out specific portions of the Applicant's disclosure providing support for the subject matter of the instant amendment or cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 50-51, 55, and 58** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stuebe et al (US Pat No. 5117827) in view of Reichstein (US Pat No. 4632119), further in view of Steffel et al (US Pat No. 4326535), and even further in view of Ishikawa et al (US Pat No. 6398710).

9. In regards to **Claim 50**, Stuebe et al disclose a system for measuring physiological parameters in the body of a patient indicative of gastroesophageal reflux, the system comprising: at least one sensor 21, 31, 61 adapted to be implanted in the body of the patient, best seen in Figure 1-2, 5A, and 6, wherein the sensor periodically measures a

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physiological parameter (i.e. pH) indicative of gastroesophageal reflux (Col.7: 57-58), and wherein the sensor periodically transmits a signal 44 indicative of the measured physiological parameter that is indicative of gastroesophageal reflux, best seen in Figure 2, 4, and 5 (Col.3: 59-60).

10. However, Stuebe et al do not teach the use of a plurality of sensors. Reichstein teaches an analogous system for measuring physiological parameters indicative of gastroesophageal reflux comprising at least two sensors 12, 14 adapted to be implanted in the body of the patient, best seen in Figure 1, wherein the second sensor 14 is used as a control to compare against the parameter (i.e. pH) obtained from the first sensor 12 (Col.4: 35-38) to effectively determine the presence of gastroesophageal reflux (col.1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stuebe et al such that a plurality (at least two) of sensors are adapted to be implanted in the body of the patient as taught by Reichstein, wherein in combination the plurality of sensors is capable of independently measuring a physiological parameter indicative of gastroesophageal reflux different from other physiological parameters indicative of gastroesophageal reflux measured independently by other sensors, to effectively produce a control pH signal against which the measured pH can be compared to accurately evaluate the presence of gastroesophageal reflux.

11. However, Stuebe et al in combination with Reichstein do not disclose each of the signals includes an identifier that is indicative of the sensor from which the signal is sent and a receiver that receives the signals from the plurality of sensors, determines a location for each sensor within an esophagus based on the identifier, and monitors the

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physiological parameter indicative of gastroesophageal reflux as based on the received signals and the determined locations.

12. Steffel et al teach an analogous system for measuring physiological parameters indicative of gastroesophageal reflux comprising a pH sensor 16, an RF transmitter 31, and a receiver 32 best seen in Figure 1 that receives the signal from the sensor to effectively monitor the physiological parameter without restricting the patient's mobility with lines and wires (Col.2: 6-9). Ishikawa et al teach that the location of a plurality of implanted sensors is determined based upon an identifier that is indicative of the sensor from which the signal is sent as an effective means to determine the location of the sensor (Col.4: 35-39; Col.5: 25-30). It is noted that Stuebe et al in combination with Reichstein already teach the plurality of sensors placed within an esophagus and that the physiological parameter (i.e. pH) indicative of gastroesophageal reflux is monitored based on its determined or known location along the esophagus. See Stuebe et al at Col.1: 59-66 and Col.4: 2-3, and also shown in Figure 6. Also see Reichstein at Col.1: 17-19, Col.3: 5-9, and Col.4: 41-43 and shown in Figure 1.

13. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stuebe et al and Reichstein such that each of the signals includes an identifier that is indicative of the sensor from which the signal is sent as taught by Ishikawa et al, and includes a receiver that receives the signals from the plurality of sensors as taught by Steffel et al, wherein in combination said receiver thus determines a location for each sensor within an esophagus based on the identifier as taught by both Steffel et al and Ishikawa et al, to effectively monitor the physiological parameter indicative of gastroesophageal reflux based on the received

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signals and the determined locations by effectively determining the location of the sensor within the esophagus using the identifier and then transmitting the signal to the receiver to enable wireless monitoring without inhibiting patient mobility to accurately indicate the presence of gastroesophageal reflux, which is determined by the change in the physiological parameter (i.e. pH) along certain portions of the esophagus.

14. In regards to **Claim 51**, the combination of Stuebe et al, Reichstein, Steffel et al, and Ishikawa et al disclose the plurality of sensors includes a pH monitor and an RF transmitter (Steffel et al element 31).

15. In regards to **Claim 55**, Ishikawa et al disclose the identifier for each of the signals comprises at least one of a frequency or a code (Col.4: 35-39).

16. In regards to **Claim 58**, Stuebe et al in combination with Reichstein, Steffel et al, and Ishikawa et al disclose the receiver 32 monitors a change in pH as a function of distance from a lower esophageal sphincter (in particular see Stuebe et al and Reichstein above).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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18. **Claims 52-54** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stuebe et al in combination with Reichstein, Steffel et al, and Ishikawa et al, further in view of Brune (US Pat No. 5984875).

19. In regards to **Claim 52**, Stuebe et al in combination with Reichstein, Steffel et al, and Ishikawa et al disclose the plurality of sensors includes a microprocessor (see element 14 Figure 3 of Stuebe et al) but do not explicitly disclose the microprocessor periodically receives a signal from the pH monitor and induces the RF transmitter to periodically send an RF signal indicative of the pH measured by the pH monitor. Brune teaches analogous implanted sensor 2 includes a microprocessor 7 that periodically receives a signal from the sensor and induces an RF transmitter 9, 10 to periodically send an RF signal indicative of the sensor (Col.6: 22-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the plurality of sensors of Stuebe et al as modified by Reichstein, Steffel et al, and Ishikawa et al to include a microprocessor that periodically receives a signal from the pH monitor and induces the RF transmitter to periodically send an RF signal indicative of the pH measured by the pH monitor as taught by Brune as an effective means to periodically wirelessly transmit the pH information signal.

20. In regard to **Claims 53-54**, Stuebe et al in combination with Reichstein, Steffel et al, Ishikawa et al, and Brune disclose the plurality of sensors with a microprocessor above but do not explicitly disclose the microprocessor enables the pH monitor during a first interval and then disables the pH monitor during a second interval, while the RF

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transmitter is enabled during the second interval and disabled during periods of each cycle other than the second interval. However, Brune does disclose a first interval which is defined as when the microprocessor 7 periodically enables the sensor to obtain a signal and a second interval which is defined as when the RF transmitter 9,10 is enabled to transmit the signal (Col.6: 35-42). Brune also teaches that battery life is conserved by disabling the respective functions i.e. keeping the sensor in sleeping mode until it is necessary to trigger the signals (Col.6: 32-35).

21. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stuebe et al as modified by Reichstein, Steffel et al, Ishikawa et al, and Brune such that during the first interval the RF transmitter is disabled and during the second interval the pH monitor is disabled, wherein the disabling occurs when the respective function is not performed, i.e. the pH monitor of the respective sensor is disabled during periods of each cycle other than the first interval and the RF transmitter is disabled during periods of each cycle other than the second interval, as an effective way to enhance the battery life conservation by only enabling the proper function as it is being used and disabling it during all other times.

22. **Claims 56-57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stuebe et al in combination with Reichstein, Steffel et al, Ishikawa et al, and Brune, further in view of Kumar et al (US Pat No. 6416471).

23. Stuebe et al in combination with Reichstein, Steffel et al, Ishikawa et al, and Brune disclose the receiver above but do not disclose the receiver worn by the patient or includes circuitry to sense the position of the patient. Kumar et al disclose an analogous

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receiver 20 worn by the patient best seen in Figure 1 as well as circuitry to sense a position of the patient (Col.11: 35-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the receiver of Stuebe et al as modified by Reichstein, Steffel et al, Ishikawa et al, and Brune, to be worn by the patient and also include circuitry to sense a position of the patient as taught by Kumar et al for ease of transportation and to improve the invention by also providing valuable information pertaining to the position of the patient respectively, wherein it is then also obvious to one within the art for the receiver to also periodically record the position of the patient for the purpose of record.

Response to Arguments

24. Applicant's arguments filed 2/18/2009 have been fully considered but they are not persuasive. Applicant contends that the above combination of references do not teach the plurality of sensors is "capable of independently measuring a physiological parameter indicative of gastroesophageal reflux different from other physiological parameters indicative of gastroesophageal reflux measured independently by other sensors." However, as recited, the claims only necessitate the plurality of implanted sensors capable of independently measuring a physiological parameter indicative of gastroesophageal reflux different from other physiological parameters indicative of gastroesophageal reflux measured independently by other sensors, wherein the other sensors are assumed to be external sensors. Furthermore, it is noted that Stuebe et al teach the use of at least two sensors, one for pH measurement and one for pressure measurement, as also acknowledged by Applicant (remarks p.4). Additionally, please

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note the §112 rejections above. Therefore, it is respectfully maintained that the combination of at least Stuebe et al, Reichstein, Steffel et al, and Ishikawa et al teach the invention above as claimed.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736